

REMARKS

Reconsideration of the present application in light of the above amendments and the following remarks is respectfully requested. Claims 1-8 and 10-16 are pending. Claim 9 has been canceled without prejudice and the content of claim 9 has been incorporated into amended claim 1 without acquiescing to the rejections and merely to facilitate allowance. No new matter has been added.

Claim Objections

Claim 4 stands objected to due to several misspellings, and capitalization errors. Applicants thank the Examiner for pointing out these oversights and note the misspellings and capitalization errors have been corrected in claim 4. Accordingly, Applicants respectfully request this objection be withdrawn.

Rejection under 35 U.S.C. § 112, Second Paragraph

Claims 1-16 stand rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which the Applicants regard as the invention. In particular, the Action alleges it is unclear what is included in the invention according to the phrase "capable of providing a detectable signal" claim 1 and its dependents. The Action further alleges the phrase in claim 13 "said non-target microorganism" lacks antecedent basis.

Applicants respectfully traverse this ground for rejection and submit one of skill in the art would clearly understand the metes and bounds of the claims when read in light of the specification. Applicants submit claims 1, 8, and 13 have been amended for clarity and without acquiescing to any rejection. As such, Applicants submit the amended claims clearly point out and distinctly claim the subject matter that is the invention. Accordingly, Applicants respectfully request this rejection be withdrawn.

Rejection under 35 U.S.C. § 102(b) First Rejection

Claims 1-6 and 8-15 stand rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Townsend *et al.* (WO 96/40980). In particular, the Action alleges the cited reference teaches detectable markers for a variety of bacteria, including those of the presently claimed invention.

Applicants traverse this ground for rejection and submit each and every element of the claims of the present invention is not present in the cited reference. In particular, Applicants submit the cited reference provides a laundry list of bacterial enzymes and discusses bacterial growth medium that may detect bacteria using three or more different enzyme substrates each hydrolyzed by a different bacterial enzyme. *See* page 19.

Applicants submit the claims have been amended and without acquiescing to any rejection. Thus, Applicants submit the claims of the present invention recite a composition for detecting a target microorganism in a sample, comprising a conditionally detectable marker and a substrate for an enzyme that is an aminopeptidase that is substantially absent from the target microorganism. Applicants submit composition is not disclosed in the cited reference and as such, each and every element of the claims is not present in the cited reference. Accordingly, Applicants respectfully request this rejection be withdrawn.

Rejection under 35 U.S.C. § 102(b), Second Rejection

Claims 1-3, 6-8 and 13-16 stand rejected under 35 U.S.C. § 102 (b) as allegedly being anticipated by Grant (U.S. Patent No. 5,849,515). In particular, the Action alleges the cited reference teaches a composition for detecting bacteria in a sample, comprising nutrient substrates, growth medium, and antibiotics against non-target bacteria.

Applicants respectfully traverse this ground for rejection and submit each and every element of the claims is not present in the cited reference. In particular, Grant discloses a culture medium that allows for selective growth and identification of *E. coli* by the addition of β -glucuronidase substrate. This substrate is selectively metabolized by *E. coli*, to the exclusion of other coliforms. *See* col. 9, lines 25-50.

Applicants submit that the claims are directed to the opposite of Grant. That is the inclusion of a substrate not turned over by the target organism. Nevertheless, and without acquiescing to the rejections, Applicants have amended the claims to facilitate allowance in that the claims are now directed to a composition for detecting a target microorganism in a sample, comprising a conditionally detectable marker and a substrate for an enzyme that is an aminopeptidase and is substantially absent from the target microorganism. Applicants submit the cited reference does not disclose the composition presently claimed, instead Grant discloses selecting for a target microorganism by the presence of the enzyme that hydrolyzes β -glucuronidase substrate. Thus, Applicants submit each and every element of the present claims is not disclosed in the cited reference. Accordingly, Applicants respectfully request this rejection be withdrawn.

Rejection under 35 U.S.C. § 102(e)

Claims 1-7 and 14-16 stand rejected under 35 U.S.C. § 102 (e) as allegedly being anticipated by Line *et al.* (US Patent No. 6,368,847). In particular, the Action alleges the cited reference teaches compositions for detecting bacteria, using nutrient medium and antibiotics.

Applicants respectfully traverse this ground for rejection and submit the claimed invention is not anticipated by the cited reference because each and every element of the claims

is not present in the cited reference. In particular, Applicants submit that while Line *et al.* reviews a laundry list of nutrient components and detectable markers used to enhance media selective for particular bacteria, it does not disclose the presently claimed invention. Applicants submit the claims of the present invention, which are drawn to a composition for detecting a microorganism that utilizes a detectable marker and a substrate for an enzyme that is substantially absent from the target microorganism.

Applicants further submit that mere mention of a particular detectable marker does not render the claims of the present invention as lacking novelty. As such, Applicants submit Line *et al.*, which is directed to multiple lists of various kinds of culture medium, does not render the presently claimed invention as lacking novelty. Accordingly, Applicants respectfully request this rejection be withdrawn.

Rejection under 35 U.S.C. 103(a), First Rejection

Claims 1-15 stand rejected as allegedly being obvious in light of Townsend (WO 9640980). In particular, the Action alleges Townsend teaches a composition for detecting viable bacteria, yeast, or fungi in a test sample by using detectable markers. The Action concedes Townsend does not specifically teach the composition comprising tetrazolium red but alleges one of skill in the art would have found it obvious to expect a reasonable amount of success detecting microorganisms using tetrazolium markers.

Applicants respectfully traverse this ground for rejection and submit one of skill in the art would not view the presently claimed invention obvious in light of the cited reference, Townsend. In particular, Applicants thank the Examiner for noting Townsend does not specifically teach using tetrazolium red. Applicants submit Townsend is directed to detecting bacteria that are able to hydrolyze three or more substrates in the culture medium, while the presently claimed invention is drawn to a composition for detecting a target microorganism in a sample by using a detectable marker and substrate that is substantially absent from the target microorganism.

Applicants submit only with hindsight would one of skill in the art arrive at the presently claimed invention upon review of Townsend. Further, Applicants submit one of skill in the art

would--at best-- render the presently claimed invention "obvious to try" in light of Townsend. As such, one of skill in the art would not deem the presently claimed invention obvious upon review of Townsend. Accordingly, Applicants respectfully request this rejection be withdrawn.

Rejection under 35 U.S.C. § 103(a), Second Rejection

Claims 1-16 stand rejected under 35 U.S.C. § 103(a) as allegedly being obvious in light of Townsend in view of Stern *et al.* (US Patent No. 5,891,709). The Action alleges Townsend teaches a composition for detecting viable bacteria, yeast, or fungi in a test sample by using detectable markers and Stern *et al.* disclose using antibiotics to select for particular bacterial strains. The Action concedes Townsend does not specifically teach using tetrazolium red as a detectable marker, or antibiotics as selection for particular bacterial strains.

Applicants respectfully traverse this ground for rejection and submit one of skill in the art would not render the presently claimed invention obvious in view of Townsend and Stern *et al.* Applicants wish to thank the Examiner for acknowledging Townsend does not specifically teach tetrazolium red or the use of antibiotics to as selective measures. Applicants submit Stern *et al.* does not remedy the deficiencies of Townsend. In particular, Applicants submit neither Townsend nor Stern *et al.* teaches a composition for detecting a microorganism in a sample comprising a detectable marker and substrate that is substantially absent from the target microorganism.

Applicants submit that Stern *et al.* disclose multiple combinations of culture medium to select bacterial strains. However, neither Townsend nor Stern *et al.* disclose using a detectable marker and substrate that is absent from the selected bacterial strain. Thus, Applicants submit one of skill in the art would not render the presently claimed invention obvious in light of Townsend and Stern *et al.* Accordingly, Applicants respectfully request this rejection be withdrawn.

The Commissioner is authorized to charge any additional fees due by way of this Amendment, or credit any overpayment, to our Deposit Account No. 19-1090.

Application No. 09/940,682
Reply to Office Action dated July 1, 2003

All of the claims remaining in the application are now believed to be allowable.
Favorable consideration and a Notice of Allowance are earnestly solicited.

Respectfully submitted,

David Townsend

SEED Intellectual Property Law Group PLLC



William T. Christiansen, Ph.D.
Registration No. 44,614

WTC:jto

Enclosure:
Postcard

701 Fifth Avenue, Suite 6300
Seattle, Washington 98104-7092
Phone: (206) 622-4900
Fax: (206) 682-6031

C:\NrPortbl\iManage\JOHNO\421843_1.DOC